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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 904,181	07 11 2001	Michael W. Leviten	R-456	1164

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DELTAGEN, INC.
1003 Hamilton Avenue
Menlo Park, CA 94025

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
1632	7

DATE MAILED: 03 12 2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/904,181	LEVITEN, MICHAEL W.
Examiner	Art Unit	
Peter Paras	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) Interview Summary (PTO-413) Paper No(s) _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a targeting construct that is homologous to the ubiquitin-specific protease gene and methods of producing the same, classified in class 435, subclass 320.1.
- II. Claims 5-10, 12 and 17-20, drawn to a transgenic cell comprising a disruption in a ubiquitin-specific protease gene, a transgenic non-human animal comprising a disruption in a ubiquitin-specific protease gene, a method of producing a transgenic mouse comprising a disruption in a ubiquitin specific protease gene, a transgenic mouse comprising a disruption in a ubiquitin-specific protease gene that exhibits increased PPI, a method of producing the same transgenic mouse, and a cell derived from the same transgenic mouse, and methods of using the same transgenics for identifying an agent that modulates the function of a ubiquitin-specific protease, classified in classes 800, 800, 800, 800, 435 and 435 subclasses 13, 18, 25, 3, 325, 455.
- III. Claims 13-15 and 22-23, drawn to methods of identifying agents that modulate the expression or modulate the function of a ubiquitin-specific protease gene in a cell *in vitro*, classified in class 435, subclass 6.
- IV. Claims 16 and 24, drawn to an unknown agent are unclassifiable.

V. Claim 25, drawn to an agent that modulates a ubiquitin-specific protease gene, classified in class 424, subclass 184.1.

VI. Claims 11 and 21, drawn to a method of identifying an agent that modulates the expression of a ubiquitin-specific protease in a transgenic non-human animal, particularly a mouse, having a disrupted ubiquitin-specific protease gene, classified in class 800, subclass 3.

The products of Inventions I, II, IV, and V each from the other are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of Groups I, II, IV, and V have different chemical structures, are made by different methods, and can be used in different methods which require different technical considerations and materially different reagents. For example, the transgenic animal non-human animal of Group II can be used as a model of disease while the targeting construct of Group I may be used to disrupt a gene in a somatic cell *in vitro*. Also, the agents of groups IV and V may have different chemical structures from each other, as well as from the targeting construct and transgenic non-human animals of Groups I and II respectively, and may be used in different methods, which require different technical considerations with respect to modulation of a ubiquitin-specific protease. Because these inventions are distinct for the reasons given above and have acquired a separate

status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups III and VI, because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups III and VI, restriction for examination purposes as indicated is proper.

The products of Inventions I, II, IV, V and the methods of Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects each from the other. The products of Groups I, II, IV, and V can be used in methods that require different technical considerations and materially different reagents from the method of Groups III and VI. The method of Group III can be practiced with products that have different chemical structures than the products of Groups I, II, IV and V. For example, the transgenic animals of Group II may be used to produce antibodies while the method of Group III may be used to identify agents that modulate the expression of a ubiquitin protease. Further, the method of Group III may be practiced with agents that

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have different chemical structures from the agents of Groups IV and V. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

A telephone call was made to Mariette Lapiz on 2/22/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 305-2758.

Peter Paras, Jr.
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Scott D. Priebe
SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER